UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF OHIO

IN RE: LOESTRIN 24 FE ANTITRUST LITIGATION

All Actions

(pending in the United States District Court for the District of Rhode Island, MDL No. 2472, C.A. No. 1:13-md-2472-S-PAS)

WARNER CHILCOTT SALES (US), LLC; WARNER CHILCOTT (US), LLC; WARNER CHILCOTT PUBLIC LIMITED COMPANY; WARNER CHILCOTT COMPANY, LLC F/K/A WARNER CHILCOTT COMPANY, INC.; WARNER CHILCOTT LABORATORIES IRELAND LIMITED; WARNER CHILCOTT HOLDINGS COMPANY III, LTD.; WARNER CHILCOTT CORPORATION; and WATSON LABORATORIES, INC.

Petitioners/Defendants,

VS.

ENVISIONRXOPTIONS and ENVISION RX OPTIONS HOLDINGS, INC.,

Respondents.

5:18 MC

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CIVIL CASE NO .:

JUDGE:

Related Pending Matter: MDL No. 2472 C.A. No. 1:13-md-2472-S (Pending in the District of Rhode Island)

MEMORANDUM OF LAW IN SUPPORT OF DEFENDANTS'
APPLICATION FOR AN ORDER COMPELLING ENVISIONRX TO PRODUCE
DOCUMENTS AND DEPOSITION TESTIMONY IN RESPONSE TO SUBPOENA

Warner Chilcott Sales (US), LLC, Warner Chilcott (US), LLC, Warner Chilcott Public Limited Company, Warner Chilcott Company, LLC f/k/a Warner Chilcott Company, Inc., Warner Chilcott Laboratories Ireland Limited, Warner Chilcott Holdings Company III, Ltd., Warner Chilcott Corporation, and Watson Laboratories, Inc. (collectively, the "Defendants"), hereby submit this memorandum of law in support of their application for an order compelling EnvisionRxOptions and Envision Rx Options Holdings, Inc. (collectively, "EnvisionRx"), to comply with subpoenas, dated September 29, 2017 (the "Subpoenas") and produce documents and deposition testimony before the June 19, 2018¹ close of fact discovery in this case.

INTRODUCTION

This is a discovery dispute in a multi-district antitrust litigation pending in the District of Rhode Island, between Defendants and EnvisionRx, a pharmacy benefits manager ("PBM") located in the Northern District of Ohio that is affiliated with one of the Plaintiffs in the underlying Rhode Island action, Retailer Rite Aid. *See In re Loestrin 24 Fe Antitrust Litig.*, No. 1:13-md-2472-WES-PAS (D.R.I.). The Plaintiffs² in the underlying litigation allege that Defendants delayed pharmaceutical manufacturers from launching a generic version of the oral contraceptive Loestrin 24 Fe ("Loestrin 24") by filing and settling "sham" patent litigation and "product hopping" from Loestrin 24 to a chewable oral contraceptive, Minastrin 24 Fe ("Minastrin 24") (collectively, the "Loestrin Products"). Defendants intend to prove that the

¹ See Case Management Order 10 at 2, Apr. 19, 2018, ECF No. 388. Unless otherwise noted, all "ECF" docket entries refer to the docket in the underlying action pending in the District of Rhode Island, *In Re Loestrin 24 Fe Antitrust Litigation*, MDL No. 2472, C.A. No. 1:13-md-2472-S-PAS.

² There are three plaintiff groups in this litigation – Direct Purchaser Plaintiffs (wholesalers); End Payor Plaintiffs (indirect purchasers consisting of nine health plan sponsors and three individuals), and Retailer Plaintiffs (retailer pharmacies) (all three groups collectively, "Plaintiffs").

³ See, e.g., End Payor Pls.' Second Am. Compl. ¶ 6, 108–09, May 9, 2016, ECF No. 165; Retailers CVS & Rite Aid Pls.' First Am. Compl. ¶ 10, 148, May 23, 2016, ECF No. 174; Retailers Walgreen et al. Pls.' First Am. Compl. ¶ 10, 151, May 23, 2016, ECF No. 175; Direct Purchaser Pls.' Third Am. Compl. ¶ 293–94, Mar. 28, 2018, ECF No. 328.

Loestrin Products are part of the larger market for oral contraceptives and compete head-to-head with many other products—crucial evidence that Defendants possess no monopoly market power and hence are not subject to antitrust scrutiny. To prove these facts, Defendants served discovery subpoenas on EnvisionRx requesting documents and deposition testimony showing that the Loestrin Products compete in the marketplace with many other drugs, and how. Despite their affiliation with Plaintiff Rite Aid, EnvisionRX refuses to provide the bulk of this discovery.

The Court in the underlying action issued a Memorandum and Order on Defendants' Motion to Compel Product Market Discovery ("Product Market Order"), finding that "documents related to the parties' competing versions of the relevant product market are relevant." The Product Market Order states that the "examination of anticompetitive effects relies on the definition of the relevant product market in which they occur. That inquiry in turn examines the reasonable economic interchangeability of a set of products, looking not at the similarity of their forms or functions, but rather at 'the extent to which purchasers will accept substitute products in instances of price fluctuation and other changes." This is consistent with the Supreme Court's statements that market definition discovery of the type Defendants seek is highly relevant in an antitrust case such as this one.

Defendants have sought product market discovery from the Plaintiffs and third parties in the underlying litigation, given its importance to the viability of Plaintiffs' claims. In response, Plaintiffs directed Defendants to their affiliated PBMs for much of the information Defendants seek. As directed, Defendants served subpoenas on those PBMS, including EnvisionRX, Plaintiff Rite Aid's affiliated PBM. But now EnvisionRX refuses to provide critical product

⁴ Mem. & Order at 11-12, Mar. 15, 2017, ECF No. 282.

⁵ *Id.* at 6.

⁶ See, e.g., Eastman Kodak Co. v. Image Tech. Servs., Inc., 504 U.S. 451, 482 (1992) ("The proper market definition . . . can be determined only after a factual inquiry into the 'commercial realities' faced by consumers.") (citation omitted).

market discovery that rebuts Plaintiffs' allegation that the Loestrin Products and their AB-rated generics are monopoly products.

As one of the largest PBMs in the nation, EnvisionRx manages prescription benefits "supporting a rapidly growing membership base of over 23 million members." PBMs like EnvisionRx play a key role in determining what pharmaceutical products insurance plans will cover, decisions which are largely influenced through negotiations with drug manufacturers. Insurance coverage, in turn, drives patients to use particular products by limiting which are available or increasing patients' copayment amounts. EnvisionRx's ability to influence patient decision-making and interchangeability among similar drugs goes directly to Defendants' key defenses: that is, that there is a broader product market of therapeutically- and economically-interchangeable oral contraceptives, and that Defendants have no monopoly power in that market. For this reason, Defendants have requested documents showing manufacturers' bids to have their pharmaceutical products covered, documents indicating why EnvisionRx included certain oral contraceptives from its formularies and preferred drug lists and excluded others, and the resulting rebate agreements with various manufacturers.

EnvisionRx baselessly refuses to produce the bulk of the information requested in Defendants' Subpoenas; there is no undue burden to produce the narrow category of documents or to provide deposition testimony. Moreover, there is no confidentiality issue that warrants withholding this highly relevant discovery because the underlying proceeding has a robust "attorneys' eyes only" protective order. To the extent EnvisionRx has additional concerns, Defendants are willing to agree to heightened protections through a supplemental protective

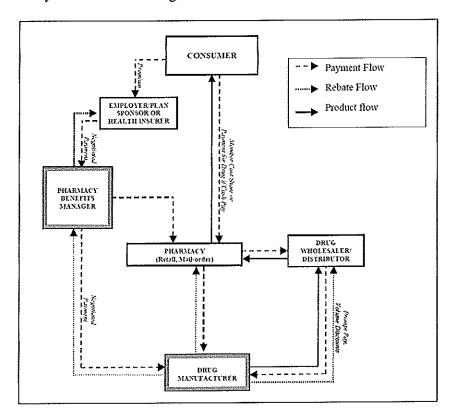
⁷ Who We Are, EnvisionRXOptions, https://www.envisionrx.com/OurDifference/WhoWeAre (last visited Apr. 20, 2018).

order, as the parties have done with other third parties. Simply put, EnvisionRx is obligated to comply with the Subpoenas so that Defendants can defend against the extensive antitrust claims brought against them.

BACKGROUND

I. THE BASIS FOR THE ENVISIONRX SUBPOENAS

To put this motion in context, it is important to understand the role of a PBM in the health insurance system. The following is an illustration:



Drug manufacturers like Warner Chilcott (shown in blue) develop and produce drugs, which are sold to wholesalers and pharmacies. Pharmacies, in turn, dispense these drugs to patients. Although some patients pay the entire cost of their medications out-of-pocket, most patients are covered by insurance. When filling a prescription, an insured often will make a co-payment to

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⁸ See Supplemental Protective Order, Mar. 28, 2018, ECF No. 375.

the pharmacy, covering part of the total cost, and the patient's insurer reimburses the pharmacy for the remaining amount.

PBMs, shown in green, play a crucial role in insurer reimbursement. PBMs administer prescription drug benefits on behalf of health plan sponsors and insurers. To do so, PBMs, among other things, develop and implement "formularies." A drug formulary is a list of prescription drugs covered by a prescription drug plan or another insurance plan offering prescription drug benefits. If a drug is included on the formulary, it is covered (i.e., reimbursed) by the plan with the patient often sharing in some of the drug cost, typically through a copayment. Drugs on a formulary are often grouped into tiers, with a patient's co-payment or coinsurance determined by the tier that the medication is on. If a drug is excluded from the formulary, plan coverage may be minimal or nonexistent, leaving the patient to pay most or all of the drug costs. PBMs develop and implement formularies and related controls to manage prescription drug usage and control costs for their plan clients. PBMs enforce their formularies through a variety of strategies, including requiring higher co-payments for certain drugs within the same therapeutic class (that is, charging the patient less for a preferred drug), or not covering non-preferred drugs at all. By positioning certain drugs on a formulary in a preferred (i.e. lower co-payment) position while excluding others, PBMs encourage the use of certain drugs; by excluding drugs from formulary, PBMs discourage the use of such non-preferred drugs.

A large PBM like EnvisionRx has enormous leverage over drug manufacturers. EnvisionRx's website boasts that it manages prescription benefits "supporting a rapidly growing membership base of over 23 million members." EnvisionRx's publicly available 2016 "Standard Formulary" states that it is a "reference tool for identifying preferred medications

⁹ Who We Are, EnvisionRXOptions, https://www.envisionrx.com/OurDifference/WhoWeAre (last visited Apr. 20, 2018).

within certain therapeutic categories."¹⁰ It also features a set of "Utilization Management protocols" for certain drug categories, including oral contraceptives.¹¹ Within these drug categories, "there are clinically interchangeable alternatives available with significant deviations in economic value. In order to maintain the highest quality of care, EnvisionRx has selected the most clinically and economically valuable agents in each class to be included on the formulary."¹² Given the large number of patients covered, EnvisionRx's decision to include or exclude drugs significantly affects drug utilization and sales.

Where therapeutically interchangeable products exist in the market, their manufacturers compete vigorously to be included on a PBM's formulary and, where possible, to be in a "preferred" position (i.e. lower co-payment) on the formulary. PBMs such as EnvisionRx are able to demand that manufacturers pay "rebates" (i.e. financial compensation) in exchange for being included on a formulary, and require additional rebates for "preferred" status. Increasingly, PBMs ask manufacturers to bid against each other to avoid being excluded from the formulary. In cases where there are dozens of brand name and generic drugs in a therapeutic class (in this case, oral contraceptives), competition among brands is particularly fierce. One National Institute of Health study shows that only 0.2% of women surveyed used Loestrin 24, and it ranked 50th out of eighty-eight different oral contraceptives. Loestrin 24 ranked well behind top ranking contraceptives Yasmin (11%) and Yaz (6%)—the products that were the subject of the successful motion to dismiss based on a lack of monopoly power in the *Yaz* antitrust litigation. Documents that show EnvisionRx solicited bids for oral contraceptives, the

¹⁰ See Standard Formulary, EnvisionRX (Oct. 2016), https://envisionrx.com/pdf/pdl.pdf.

¹¹ Id.

¹² *Id*.

¹³ ECF 245 at Ex. N at 13.

¹⁴ See Bayer Schering Pharma AG v. Sandoz, Inc. ("Yaz"), 813 F. Supp. 2d 569, 576–78 (S.D.N.Y. 2011) (rejecting as implausible plaintiff's proposed product market comprising of only two branded oral contraceptive drugs).

bid documents associated with those bids, and the rebate agreements associated with those bids are highly relevant to defining the relevant market.

II. THE UNDERLYING ACTION, THE SUBPOENAS & NEGOTIATIONS

On January 13, 2017, Defendants filed a motion to compel product market discovery from all of the Plaintiffs in the underlying litigation, including Retailer Plaintiff Rite Aid. In that motion, Defendants sought critical discovery relevant to assessing the relevant product market. This discovery included PBM-related discovery regarding formularies and formulary tier placement and adjustments. On March 15, 2017, Magistrate Judge Sullivan entered an order granting Defendants' motion to compel, finding that "documents related to the parties' competing versions of the relevant product market are relevant."

On September 13, 2017, the parties in the underlying litigation had an informal conference with Magistrate Judge Sullivan regarding product market discovery. Both before and during that conference, Rite Aid objected to the portions of the requested discovery that pertained to PBM discovery, claiming it had no control over its related entity EnvisionRx because: "The key individuals in Rite Aid's purchasing department have little to no interaction with EnvisionRx; in fact, EnvisionRx has its own purchasing group. Rite Aid has no access to EnvisionRx documents or data" and "has no email or custodial files from individuals employed at EnvisionRx." 19

After the September 13, 2017 conference with Magistrate Judge Sullivan, Defendants

¹⁵ See Defs.' Motion to Compel Product Market Disc., Jan. 13, 2017, ECF No. 244.

¹⁶ Mem, of Law in Support of Defs.' Motion to Compel Product Market Disc. at 1–4, Jan. 13, 2017, ECF No. 244-1.

¹⁷ Id. at 5-9.

¹⁸ Mem. & Order at 10-11, Mar. 15, 2017, ECF No. 282.

¹⁹ See Letter from E. Bloom (Counsel for Retailer Plaintiff Rite Aid) to A. Daker at 3, Aug. 1, 2017, attached as Ex. A.

served subpoenas on EnvisionRxOptions²⁰ and Envision Rx Options Holdings, Inc.²¹ EnvisionRx, like Retailer Plaintiff Rite Aid, has refused to produce key discovery relating to the relevant product market. To date, EnvisionRx has only produced

for a portion of the relevant time period²² and has agreed to produce some other categories of documents including select P&T committee minutes.²³

Despite Defendants' narrowing of the Subpoenas, EnvisionRx has refused to produce bid documents and rebate related discovery, and to provide a witness for deposition regarding any topic.²⁴ As a result, EnvisionRx's production does not show the rebates competing manufacturers offered to EnvisionRx; does not explain how and why EnvisionRx, in the documents it produced,

documents also do not address related questions concerning the placement of certain oral contraceptives on EnvisionRx's formularies and preferred drug lists over others. Defendants will not be able to ascertain that information from the other categories of documents EnvisionRx has agreed to produce.²⁶

Although the Subpoenas initially sought bid solicitations, responses, and rebate

²⁰ Subpoena to EnvisionRxOptions, attached as Ex. B; see also April 20, 2018, Decl. of Angela D. Daker at ¶ 2, attached as Ex. C.

²¹ Subpoena to Envision Rx Options Holdings, Inc. at ¶ 4, attached as Ex. D; see also Ex. C at ¶ 3.

²² See Ex. C at ¶ 6 (explaining that the relevant time period in the EnvisionRx Subpoenas is February 1, 2006 to December 31, 2015).

²³ See id. at ¶¶ 5-6, and n.2.

²⁴ See id. at ¶ 6.

²⁵ The preceding redacted sentences contains information from documents that have been marked either Confidential or Highly Confidential – Attorney's Eyes Only pursuant to a protective order in the underlying litigation. A copy of the protective order can be found at ECF No. 79. The Defendants intend to supplement the record with an unredacted version of this Memorandum pending the Court's ruling on a motion to seal.

²⁶ See id. at ¶ 5.

agreements as to Loestrin 24, Minastrin, and the Ten Oral Contraceptives,²⁷ Defendants subsequently narrowed the scope to rebate agreements with Bayer (manufacturer of key competitors Yaz, Yasmin, and Beyaz) and Janssen (manufacturer of key competitors Ortho Tri-Cyclen and Ortho Tri-Cyclen Lo, Ortho Cyclen, and Ortho-Cept).²⁸ EnvisionRx rejected this offer.²⁹ Accordingly, Defendants request that this Court compel EnvisionRx to provide the following discovery:

- Documents showing EnvisionRx's bid solicitations to manufacturers regarding the Loestrin Products and the Ten Oral Contraceptives, the manufacturers' responses, and EnvisionRx's consideration of and decisions on those bids (collectively, the "bid documents") (Request Nos. 2, 3, 4, and 13);
- EnvisionRx's rebate agreements with: (a) Bayer AG ("Bayer"), manufacturer of Yaz, Yasmin, and Beyaz; and (b) Janssen Pharmaceuticals, Inc. ("Janssen"), manufacturer of Ortho Tri-Cyclen and Ortho Tri-Cyclen Lo, Ortho Cyclen, and Ortho-Cept, related to Bayer and Janssen's competitor drugs to the Loestrin Products (the "rebate agreements") (Request Nos. 10 and 11); and
- Deposition testimony regarding: (a) the documents and topics EnvisionRx has already produced or agreed to produce; (b) EnvisionRx's consideration of manufacturers' bids and its decisions regarding formulary inclusion or exclusion for the Loestrin Products and the Ten Oral Contraceptives (Topics Nos. 2, 3, 4, and 13); (c) EnvisionRx's rebate agreements with manufacturers regarding the Loestrin Products and the Ten Oral Contraceptives (Topics Nos. 10 and 11); and (d) the authentication of the documents EnvisionRx has produced (Topic No. 12).

ARGUMENT

I. THE REQUESTED DISCOVERY IS CRUCIAL TO THIS LITIGATION

A. MARKET DEFINITION AND DEFENDANTS' LACK OF MONOPOLY POWER ARE KEY ISSUES

²⁷ Although Defendants maintain that the relevant product market in this case consists of dozens of oral contraceptives, Defendants have agreed to limit certain discovery based upon the Ten Oral Contraceptives, all of which are interchangeable with Loestrin 24. The Ten Oral Contraceptives consist of: Alesse, Beyaz, Femcon/Ovcon, Nordette, Ortho Cyclen, Ortho Tri Cyclen, Ortho Tri Cyclen Lo, Ortho-Cept/Desogen, Yasmin, and Yaz, as well as these drugs' AB-rated generics (the "Ten Oral Contraceptives"). See Defs.' Mem. of Law in Support of Mot. to Compel Product Market Disc. at 2, Jan. 13, 2017, ECF No. 244-1.

²⁸ See Ex. C at ¶ 7.

²⁹ See id.

Plaintiffs allege that Defendants exercise power in a narrow pharmaceutical product market that consists only of the Loestrin Products and their generic equivalents.³⁰ Defendants intend to show that, in reality, the relevant market is broader, much more dynamic, and includes a number of branded and generic oral contraceptives. Defendants intend to prove that manufacturers of branded oral contraceptives in particular vigorously compete with Defendants and each other, including by seeking preferred positions on formularies and seeking to avoid being excluded from formularies. Such evidence of industry practice is crucial—and, indeed, foundational—to defining a relevant market. *See Brown Shoe Co. v. United States*, 370 U.S. 294, 325 (1962) (establishing cross-elasticity of demand test and noting industry practice can be a key piece of evidence in defining the relevant market).³¹

Magistrate Judge Sullivan in the underlying litigation has already found that "documents related to the parties' competing versions of the relevant product market are relevant." Other courts have similarly relied on proof of competition between branded pharmaceutical manufacturers in determining the relevant product market and finding no antitrust violation. See Mylan Pharms. Inc. v. Warner Chilcott PLC, 2015 WL 1736957, at *11 (E.D. Pa. Apr. 16, 2015), aff'd, Mylan Pharms., Inc. v. Warner Chilcott PLC, 838 F.3d 421, 436-37 (3d Cir. 2016) ("Doryx"). In Doryx, the Third Circuit held that the plaintiffs' position that the product market was limited to the branded drug and its generic equivalent was "further undercut" where "health

 $^{^{30}}$ See Mem. & Order at 6–7, Mar. 15, 2007, ECF 282 (citing ECF No. 164 \P 303; ECF No. 165 \P 303; ECF No. 174 \P 179; ECF No. 175 \P 182).

³¹ Product market discovery is typical in pharmaceutical antitrust cases, including this case. See Mem. & Order at 10–11, ECF 282 (finding that "documents related to the parties' competing versions of the relevant product market are relevant."); In re Suboxone (Buprenorphine Hydrochloride & Naloxone) Antitrust Litig., No. 13-MD-2445, 2016 U.S. Dist. LEXIS 83499, at *7 (E.D. Pa. June 28, 2016) ("without the benefit of a fully developed record, rulings regarding the market dynamics in this context would be premature and speculative"); In re Wellbutrin XL Antitrust Litig., No. 2:08-cv-02431- MAM (E.D. Pa. Mar. 12, 2012) ECF No. 175 at 2 (ordering product market documents relevant to competition with other antidepressants to be produced); Meijer, Inc.v. Warner Chilcott Holdings, Co. III, Ltd., 245 F.R.D. 26, 30–32 (D.D.C. 2007) (discovery regarding contraceptives interchangeable with Ovcon ordered to be produced).

³² Mem. & Order at 10-11, ECF No. 282.

insurers and other managed care providers encouraged the widespread substitution of numerous other [alternatives]." *Id.* at 436; *see also Yaz*, 813 F. Supp. 2d at 576–78 (rejecting plaintiff's proposed product market comprising only the two branded oral contraceptive drugs at issue and their AB-rated generics as "far too narrow" and making "no rational or economic sense," in large part because there are "dozens" of oral contraceptives).

Evidence obtained from PBMs, like EnvisionRx, and managed care organizations often is critical to a court's determination of the relevant market. See Schering-Plough Corp., Upsher-Smith Labs. & Am. Home Prods. Corp., FTC Docket No. 9297 at 10–11 (June 2002) (initial decision) (relying on testimony from then-largest PBM in defining relevant market) aff'd, Schering-Plough v. FTC, 402 F.3d 1056 (11th Cir. 2005); Kaiser Found. v. Abbott Labs., U.S. Dist. LEXIS 107512, at *8–9 (C.D. Cal. Oct. 8, 2009) (rejecting plaintiffs' product market contention in part because "it is undisputed that Plaintiff treated Hytrin as interchangeable with other alpha-blockers in . . . its formulary decisions – including its decisions, based on price, to replace Hytrin with other alpha-blockers in certain formularies"); Purdue Pharma Prods. L.P. v. Par Pharm., Inc., 642 F. Supp. 2d 329, 352 (D. Del. 2009) (finding that product "attained no more than half of a percent of total prescriptions of the relevant market for pain medications" in part based on its "tier 3" non-preferred formulary status). If produced here, the requested materials may prove just as important. Indeed, this discovery may be case-dispositive.

B. BID DOCUMENTS ARE HIGHLY RELEVANT

The bid documents Defendants seek are critical to establish that Defendants possess no monopoly power. In *Doryx*, the Third Circuit accepted the defendant's evidence showing cross-elasticity of demand between defendant's pharmaceutical product and other tetracyclines. *See Doryx*, 838 F.3d at 437. "Cross-elasticity of demand is a measure of the substitutability of

products from the point of view of buyers. More technically, it measures the responsiveness of the demand for one product [X] to changes in the price of a different product [Y]." *Id.* (internal marks omitted). Thus, if Defendants can show that when the price of the Loestrin Products *increased*, their sales *decreased*, and the sales of other oral contraceptives *increased*—that is evidence of cross-elasticity of demand and no monopoly power. *See id.*

This is precisely what the bid documents would show. These would reveal EnvisionRx's economic assessment in deciding which drugs to include and exclude from its formulary. They would show EnvisionRx's decision regarding the placement or exclusion of Loestrin Products or other competitor oral contraceptives, to increase for patients the price of the Loestrin Products relative to other drugs in the therapeutic class, and thereby to encourage patients instead to use other therapeutically interchangeable oral contraceptives. This is the essence of cross-elasticity, and it may prove case determinative here, as in *Doryx*.

C. REBATE AGREEMENTS ARE HIGHLY RELEVANT

EnvisionRx's rebate agreements with manufacturers of competing oral contraceptives are highly relevant as well. These agreements would show the economic terms that EnvisionRx ultimately agreed to include certain oral contraceptives on its formularies while excluding others. Such information is key evidence of the economic substitutability between the Loestrin Products and their competitors.

Moreover, rebate agreements often include agreed-upon market definitions. Manufacturers may pay an "access rebate" when a product is given preferred formulary placement, and an additional "performance rebate" based on an increase in the product's market share relative to other competing products.³³ Where a performance rebate is present, the rebate

³³ See Peter R. Kongstvedt, Essentials of Managed Health Care 266 (6th ed. 2013).

agreement typically defines the market in which a drug competes so that the increase or decrease in market share relative to competing drugs can be calculated. See J.B.D.L. Corp. v. Wyeth-Ayerst Labs., Inc., 485 F.3d 880, 884–85 (6th Cir. 2007) ("Wyeth consistently tied the size of rebates to the market share of a particular class of drugs, with a sufficiently low market share resulting in the loss of all rebates on particular products."). Agreed-upon market definitions in arm's-length contracts between key players in the sale of oral contraceptives is critical evidence of what the entire industry—not just Defendants—understood the market to be.

D. THE DEPOSITION TESTIMONY IS HIGHLY RELEVANT

Defendants seek deposition testimony regarding the topics and documents for which EnvisionRx has agreed to produce, its manufacturer bids, its decisions to include on and exclude from its formularies competing oral contraceptives, and its rebate agreements for oral contraceptives. These topics go directly to the issues of therapeutic and economic interchangeability of the Loestrin Products with other oral contraceptives—issues that are critical to market definition and monopoly power. *See Doryx*, 838 F.3d at 436–38. Defendants also seek deposition testimony to authenticate documents for use at trial, given their importance to this case. These topics are narrow, focused, and highly relevant to the issues in this case.

II. ENVISIONRX HAS NO BASIS TO WITHHOLD THE REQUESTED DISCOVERY

A. NO UNDUE BURDEN EXISTS

EnvisionRx faces no undue burden in producing the requested discovery, especially taking into consideration its direct relationship to Plaintiff Rite Aid. The burden of proving that a subpoena is oppressive is a "heavy" one. *See White Mule Co. v. ATC Leasing Co. LLC*, 2008 U.S. Dist. LEXIS 51344, at *12 (N.D. Ohio June 25, 2008). The potential hardship to the party subject to the subpoena must be balanced against the relevance of the discovery sought and the

requesting party's need for the discovery. See Vaughan v. City of Shaker Heights, No. 1:10 CV 609, 2013 U.S. Dist. LEXIS 126094, at *16 (N.D. Ohio Sept. 4, 2013) ("In determining whether a subpoena imposes an undue burden, a court considers such factors as relevance, the need of the requesting party for the documents, the breadth of the document request, the time period covered by it, the particularity with which the documents are described and the burden imposed.") (citation and alterations omitted); FTC v. Trudeau, No. 5:12MC35, 2012 U.S. Dist. LEXIS 160545, at *5 (N.D. Ohio Nov. 8, 2012) ("the subpoena should be enforced unless the documents are privileged or the subpoena is unreasonable, oppressive, annoying, or embarrassing." (internal quotations omitted)). Here, EnvisionRx faces no undue burden. EnvisionRx is a sophisticated, multibillion-dollar enterprise that does not lack the resources to produce the requested materials and is directly related Plaintiff Rite Aid.

The documents and deposition testimony sought are narrowly tailored to focus on a small number of drugs on highly specific topics. Any burden on EnvisionRx is outweighed by the importance of this product market discovery and Defendants' substantial need to obtain evidence from this leading pharmaceutical market participant.

B. ENVISIONRX'S CONFIDENTIALITY CONCERNS CAN BE ADDRESSED THROUGH THE PROTECTIVE ORDER

The protective order entered in this case affords third parties like EnvisionRx the ability to designate its documents as "Confidential" or "Highly Confidential," and strictly limits who may have access to such designated material.³⁴ There is no reason to believe that EnvisionRx's interest in maintaining confidentiality will be harmed or that competitively sensitive information will be disclosed to its competitors. *See In re Mushroom Direct Purchaser Antitrust Litig.*, No. 06-0620, 2012 U.S. Dist. LEXIS 12319, at *42 (E.D. Pa. Jan. 31, 2012) (protective orders are

³⁴ See Stipulation & Protective Order at 3, Feb. 11, 2014, ECF No. 79.

sufficient to protect discovery of confidential business information); *United States v. Dean Foods Co.*, No. 10-CV-59, 2011 U.S. Dist. LEXIS 13900, at *7 (E.D. Wis. Feb. 3, 2011) (ordering production from a non-party competitor, noting that the protective order ensured against the improper us of the non-party's business records); *DatCard Sys., Inc. v. PacsGear, Inc.*, No. 11-mc-0025, 2011 U.S. Dist. LEXIS 67648, at *6 (D. Minn. Apr. 25, 2011) (third party's claim "concerning the disclosure of confidential information is unfounded in light of the Protective Order in the underlying case."). To the extent EnvisionRx can articulate any concerns with the existing protective order, Defendants are willing to agree to an amended or supplemental protective order providing heightened protections to EnvisionRx, as the parties have done with other third-parties in this case.³⁵

CONCLUSION

For these reasons, Defendants respectfully request that the Court grant this motion and compel EnvisionRx to provide, before the June 19, 2018, close of fact discovery:

- 1. Documents showing EnvisionRx's bid solicitations to manufacturers regarding the Loestrin Products and the Ten Oral Contraceptives, the manufacturers' responses, and EnvisionRx's consideration of and decisions on those bids (collectively, the "bid documents") (Request Nos. 2, 3, 4, and 13);
- 2. EnvisionRx's rebate agreements with: (a) Bayer, manufacturer of Yaz, Yasmin, and Beyaz; and (b) Janssen, manufacturer of Ortho Tri-Cyclen and Ortho Tri-Cyclen Lo, Ortho Cyclen, and Ortho-Cept related to Bayer and Janssen's competitor drugs to Loestrin (the "rebate agreements") (Request Nos. 10 and 11); and
- 3. Deposition testimony regarding: (a) the documents and topics EnvisionRx has already produced or agreed to produce; (b) EnvisionRx's consideration of manufacturers' bids and its decisions regarding formulary inclusion or exclusion for the Loestrin Products and the Ten Oral Contraceptives (Topics Nos. 2, 3, 4, and 13); (c) EnvisionRx's rebate agreements with manufacturers regarding the Loestrin Products and the Ten Oral Contraceptives (Topics Nos. 10 and 11); and (d) the authentication of the documents EnvisionRx has produced (Topic No. 12).

³⁵ See Supplemental Protective Order, Mar. 28, 2018, ECF No. 375.

Dated: April 20, 2018

Respectfully submitted,

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Attorneys for Petitioners/Defendants

CERTIFICATE OF SERVICE

On April 18, 2018, Counsel for EnvisionRx has agreed to accept service of this Motion via e-mail. I hereby certify that a true and correct copy of the foregoing is being served on James Rollinson, counsel for EnvisionRx, via electronic mail at jrollinson@bakerlaw.com this 20th day of April, 2018. The foregoing is also being served via electronic mail on counsel of record in *In Re Loestrin 24 Fe Antitrust Litigation*, MDL No. 2472, C.A. No. 1:13-md-2472-S-PAS (D.R.I.).

One of the Attorneys for Defendants/Petitioners